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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/756,173 | 01/12/2004 | Claudio I. Zanelli | 022105-000100US | 2102 |

20350 7590 03/26/2007
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| EXAMINER |
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PAPAPIETRO, JACQUELINE M

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| ART UNIT | PAPER NUMBER |
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3739

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 03/26/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/756,173

Applicant(s)

ZANELLI ET AL.

Examiner

Jacqueline Papapietro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2004 and 6/18/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/11/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: WO 02/09813 A1 (Masotti).

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Claim Objections

Claims 4-20 and 22-23 are objected to because of the following informalities:

Claim 4 recites "the hair follicles" in line 4; there is lack of antecedent basis for this limitation in the claim. Claim 8 recites "scanning an acoustic transducer" in line 5 and "positioning an acoustic transducer" in line 7. It is unclear if this is the same acoustic transducer or two distinct transducer⁵. Claims 9 and 10 recite "the transducer" in the second line of each claim. It is unclear to which transducer each instance of "the transducer" refers. Claim 12 recites "a transducer" in line 2 and claim 13 recites "a transducer surface" in line 2. Again, it is unclear if these recitations are distinct or if they are meant to refer to one of the previously mentioned transducers. Claim 8 recites "the locations" in lines 5-6; there is insufficient antecedent basis for this limitation. Claim 17 recites "the ablative energy" in line 1 and "each hair follicle" in line 2. There is

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insufficient antecedent basis for these limitations in the claim. It is assumed that "and" in line 2 of claim 19 is meant to be "are." Claim 20 recites "said imaged locations" in line 3 and "the location" in line 4. There is insufficient antecedent basis for these limitations in the claim. In claim 22, "a" should be "an" in line 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the step of "immobilizing a transducer platform" in line 3, and then recites "the mobilized transducer platform" in line 6. This is confusing and unclear. Further, there is insufficient antecedent basis for "the mobilized transducer platform" in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (US 2005/0143677 A1).

Young discloses a method for removing hair from a patient's skin (paragraph 0035), said method comprising: transcutaneously focusing high intensity acoustic energy (paragraph 0014 lines 6-7) at hair follicles beneath the skin (paragraph 0021 lines 3-4), wherein the acoustic energy is focused at predetermined follicle location (paragraph 0024).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-7 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young as applied to claims 1 and 2 above, and further in view of Watkins et al (US 5769790).

Regarding claims 3-7, Young discloses the method as described above, but does not disclose the method wherein follicle locations are determined by acoustic imaging. Watkins teaches a method for delivering therapeutic ultrasound to a desired location, wherein ultrasound imaging is used to localize a target volume prior to applying therapeutic levels of ultrasound imaging (column 2 lines 26-35). The method comprises scanning an acoustic transducer (28, Fig 1) over an area in the patient to identify target locations; and focusing high intensity acoustic energy at the identified target (column 4 lines 43-50). Watkins teaches the method wherein a single acoustic transducer is used both to scan/image and to deliver the focused high intensity acoustic energy (26', Fig 2, column 6 lines 20-21); or wherein different acoustic transducers are used (26 and 28, Fig 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified Young by scanning an acoustic transducer, either distinct or the same as the therapeutic transducer, over the desired area as taught by Watkins in order to locate the desired treatment sites (the hair follicles).

Regarding claims 8-10, Watkins teaches immobilizing a transducer platform (38, Fig 2) over a target area, and completing the steps are described above. The transducer is mechanically advanced in X- and Y- directions over an imaging plane to known coordinates by a positioning system (38) and controller (12, Fig 3). Because the imaging transducer is the therapeutic transducer, the scanning and positioning transducers are advanced to the same coordinates. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the

positioning system as taught by Watkins in the method of Young in view of Watkins, as described above in order to accurately position the transducer(s).

Regarding claims 18 and 19, Watkins further teaches producing an image of the scanned area and designating which target areas are to be ablated (column 4 lines 46-50). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the steps of producing an image of the scanned area and designating which hair follicles should be ablated, as taught by Watkins, in the method of Young in order to precisely determine target locations for the high intensity focused acoustic energy.

Regarding claims 20-23, 27, and 28, Young discloses a system for hair removal, as described above, but does not disclose imaging hair follicles or tracking the location of the transducer. Watkins teaches a system for focused ultrasound therapy, said system comprising: a transducer (26) selectively operable to image a target zone and to acoustically ablate hair follicles at said target zones (the target zones being hair follicles); means for tracking the location of the transducer over a patient's skin surface (positioning system, 38); and a controller (12, Fig 3) for acquiring image data from the transducer and directing high intensity acoustic energy (see Fig 3) to selected ones of the imaged target zones (hair follicles); wherein the tracking means comprises a transducer platform (38, Fig 2) adapted to be engaged against the patient's skin; and a drive system (mechanical positioning system, column 3 lines 50-52) for advancing the transducer over a planar region defined by the platform (the mechanical positioning system has three or more axes of motion, but could be advanced in the X- and Y-

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directions only), wherein the position of the transducer can be both selected and recorded (column 4 lines 39-50). Watkins also teaches the system further comprising a display which provides a visual depiction of the target zone (22) and means for a user to designate which of the areas in the visual depiction are to be ablated (column 2 lines 44-49 and 63-57). Watkins is silent regarding the accuracy of the positioning system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the focused ultrasound system taught by Watkins in the hair removal system of Young in order to precisely ablate the desired hair follicles. It also would have been obvious to make the motion position very accurate and repeatable to ± 0.01 mm due to the small size of the hair follicles being targeted and ablated.

Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Watkins as applied to claim 4 above, and further in view of Martin et al (US 6432067 B1).

Young in view of Watkins discloses the method as in claim 4, but is silent regarding the method of transcutaneously focusing. Martin teaches a method for utilizing high intensity focused ultrasound wherein focusing comprises adjusting the depth of focus by translating a transducer along a vertical line (column 10 lines 55-58). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the focusing method as taught by Martin in the method of Young in view of Watkins in order to focus the acoustic energy on the desired hair follicle location.

Claims 11, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Watkins as applied to claim 4 above, and further in view of Weng et al (US 6719694 B2).

Young in view of Watkins discloses the method of claim 4, but does is silent regarding the method of transcuteaneously focusing. Weng teaches a method for focusing high intensity acoustic energy comprising adjusting the depth of focus by adjusting the curvature of a transducer surface (column 11 lines 58-61, Fig 13A) and by controlling the operation of a phased array transducer (column 15 lines 32-35, Figs 17A-17C). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the focusing methods as taught by Weng in the method of Young in view of Watkins in order to focus the acoustic energy on the desired hair follicle location.

Claims 15-17 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young in view of Watkins as applied to claim 4 above, and further in view of Masotti (WO 02/09813 A1).

Young in view of Watkins discloses the method as in claim 4, but no depth for focusing the high intensity acoustic energy is disclosed. Masotti teaches applying ultrasonic waves to a hair follicle wherein the high intensity acoustic energy is focused at a depth beneath the skin the range from 1 mm to 6 mm and at a width in the range from 0.1 mm to 0.3 mm (page 12, lines 12-14), wherein the high intensity acoustic

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energy is delivered under conditions to raise the temperature at the hair follicle to at least 50°C (page 6 line 31), wherein the energy is delivered in an amount from 0.1 J to 10 J (page 12 lines 8-9) for a time of at least 0.1 sec (page 12 lines 9-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Young in view of Watkins by focusing and delivering the acoustic energy as taught by Masotti in order to effectively ablate the targeted follicle.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Papapietro whose telephone number is (571) 272-1546. The examiner can normally be reached on M-F 9am-5:30pm.

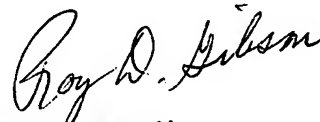
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jacqueline Papapietro
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ROY D. GIBSON
PRIMARY EXAMINER